

12 January 2009

## Proposal to amend restrictions on musculoskeletal pharmaceuticals and to reduce the subsidy for EC aspirin

### *Proposal summary*

PHARMAC is seeking feedback on a proposal to reduce the subsidy for EC aspirin and to alter the restrictions applying to various pharmaceuticals in the Musculoskeletal System therapeutic group with effect from 1 March 2009 as follows:

#### *Aspirin tab EC 300 mg*

The subsidy for aspirin tab EC 300 mg would be reduced, via the application of reference pricing, to the level of aspirin tab dispersible 300 mg.

#### *Alendronate sodium +/- cholecalciferol (Fosamax/Fosamax Plus)*

The applicant type for both the Osteoporosis and Paget's Disease Special Authorities would be changed to "relevant practitioner."

For the Osteoporosis Special Authority, the renewal criteria for 1-year approvals (underlying cause – glucocorticosteroid therapy) would be amended to allow lifetime renewals where the patient now meets the criteria for "underlying cause – osteoporosis" applications.

#### *Pamidronate disodium*

The Special Authority would be removed, meaning that prescriptions would be subsidised for any indication.

*Calcitonin, auranofin, penicillamine, sodium aurothiomalate, baclofen, dantrolene sodium*  
The Hospital pharmacy [HP3]-Specialist restriction would be removed from calcitonin, and the Retail pharmacy-Specialist restriction would be removed from auranofin, penicillamine, sodium aurothiomalate, baclofen and dantrolene sodium.

Further details of the proposal can be found on the following pages.

### *Feedback sought*

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Thursday 29 January 2009** to:

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All feedback received before the closing date will be considered when a decision is made on this proposal by PHARMAC's Board (or Chief Executive under delegated authority).

## ***The details of the proposal***

### *Aspirin tab EC 300 mg*

Enteric coated (EC) aspirin 300 mg tablets are currently listed in Section B of the Pharmaceutical Schedule at a subsidy of \$7.25 per pack of 100 tablets. EC aspirin is not fully subsidised, such that a manufacturer's surcharge applies equating to approximately \$1.60 per pack of 100 tablets (charge to the patient including mark-ups and GST).

Under this proposal, the subsidy for EC aspirin 300 mg tablets would be reduced, via the application of reference pricing, to the level of dispersible aspirin 300 mg tablets as follows:

<b>Chemical</b>	<b>Presentation</b>	<b>Subsidised brand name</b>	<b>Pack size</b>	<b>Current subsidy (price)</b>	<b>New subsidy (price)</b>
Aspirin	Tab EC 300 mg	Aspec 300	100	\$7.25 (\$8.10)	\$2.15 (\$8.10)

This would mean that a higher manufacturer's surcharge would apply to aspirin tab EC 300 mg, equating to approximately \$11.00 per pack of 100 tablets (charge to patients including mark-ups and GST), unless the supplier decided to reduce its price.

At its last meeting in March 2008, the Analgesic Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) advised PHARMAC that the enteric coating did not provide any clinical benefit over the 300 mg dispersible formulation, and recommended that the subsidy for aspirin EC 300 mg tablets be reduced to the same level as aspirin dispersible 300 mg tablets. This proposal results from that advice.

### *Alendronate sodium (Fosamax) and alendronate sodium with cholecalciferol (Fosamax Plus)*

The Special Authority for 'Alendronate for Osteoporosis' that applies to alendronate sodium tab 70 mg and alendronate sodium tab 70 mg with cholecalciferol 2800 iu would be amended as detailed below (additions in bold, deletions in strikethrough).

The changes to the renewal criteria would mean that patients who have a 1-year approval under the "underlying cause - glucocorticosteroid therapy" criteria then later meet the "underlying cause – osteoporosis" criteria would be able to apply for a lifetime renewal.

#### SA0797 Special Authority for Subsidy

Initial application – (Underlying cause - Osteoporosis) ~~only from a relevant specialist or vocationally registered general practitioner~~ **from any relevant practitioner**. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mass density (BMD)  $\geq 2.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -2.5$ ); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score  $\leq -3.0$ .

Initial application – (Underlying cause - glucocorticosteroid therapy) ~~only from a relevant specialist or vocationally registered general practitioner~~ **from any relevant practitioner**. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The patient is receiving systemic glucocorticosteroid therapy ( $\geq 5$  mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months ~~and has either~~; and
- 2 Either:
  - 2.1 **The patient has** documented BMD  $\geq 1.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -1.5$ ); or
  - 2.2 **The patient has a** history of one significant osteoporotic fracture demonstrated radiologically.

Renewal – (**Underlying cause was, and remains, glucocorticosteroid therapy**) ~~only from a relevant specialist or vocationally registered general practitioner~~ **from any relevant practitioner**. Approvals valid for 1 year where the patient is continuing systemic glucocorticosteroid therapy ( $\geq 5$  mg per day prednisone equivalents).

Renewal – (**Underlying cause was glucocorticosteroid therapy but patient now meets the ‘Underlying cause – osteoporosis’ criteria**) ~~from any relevant practitioner~~. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 **History of one significant osteoporotic fracture demonstrated radiologically and documented bone mass density (BMD)  $\geq 2.5$  standard deviations below the mean normal value in young adults (i.e. T-Score  $\leq -2.5$ ); or**
- 2 **History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or**
- 3 **History of two significant osteoporotic fractures demonstrated radiologically; or**
- 4 **Documented T-Score  $\leq -3.0$ .**

Notes:

a) Evidence used by National Institute for Health and Clinical Excellence (NICE) guidance indicates that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score  $\leq -2.5$ , and therefore do not require BMD measurement for treatment with bisphosphonates.

b) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

c) In line with the Australian guidelines for funding alendronate, a vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

The Special Authority for alendronate for Paget’s Disease that applies to alendronate sodium tab 40 mg would be amended as detailed below (additions in bold, deletions in strikethrough).

SA0467 Special Authority for Subsidy

Initial application ~~only~~ from **any relevant specialist practitioner**. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Paget's disease; and
- 2 Any of the following:
  - 2.1 Bone or articular pain; or
  - 2.2 Bone deformity; or
  - 2.3 Bone, articular or neurological complications; or
  - 2.4 Asymptomatic disease, but risk of complications due to site (base of skull, spine, long bones of lower limbs); or
  - 2.5 Preparation for orthopaedic surgery.

Renewal ~~only~~ from **any** relevant **specialist practitioner**. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

### *Pamidronate disodium*

The Special Authority would be removed as follows, meaning that prescriptions would be subsidised for any indication.

#### ~~SA0091 Special Authority for Subsidy~~

~~Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:~~

~~Either:~~

- ~~1 Paget's disease; or~~
- ~~2 Both:~~
  - ~~2.1 Patients under hospice care; and~~
  - ~~2.2 Either:~~
    - ~~2.2.1 Tumour induced hypercalcaemia; or~~
    - ~~2.2.2 Tumour induced osteolysis without hypercalcaemia.~~

~~Renewal only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.~~

### *Calcitonin, auranofin, penicillamine, sodium aurothiomalate, baclofen, dantrolene sodium*

The Hospital pharmacy [HP3]-Specialist restriction would be removed from calcitonin, and the Retail pharmacy-Specialist restriction would be removed from auranofin, penicillamine, sodium aurothiomalate, baclofen and dantrolene sodium as follows (deletions in strikethrough):

~~CALCITONIN –Hospital pharmacy [HP3]-Specialist~~

~~AURANOFIN –Retail pharmacy-Specialist~~

~~PENICILLAMINE –Retail pharmacy-Specialist~~

~~SODIUM AUROTHIOMALATE –Retail pharmacy-Specialist~~

~~BACLOFEN –Retail pharmacy-Specialist~~

~~DANTROLENE SODIUM –Retail pharmacy-Specialist~~